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Guidance for the Reregistration of Pesticide Products Containing Trimethacarb as the Active Ingredient

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Washington, DC

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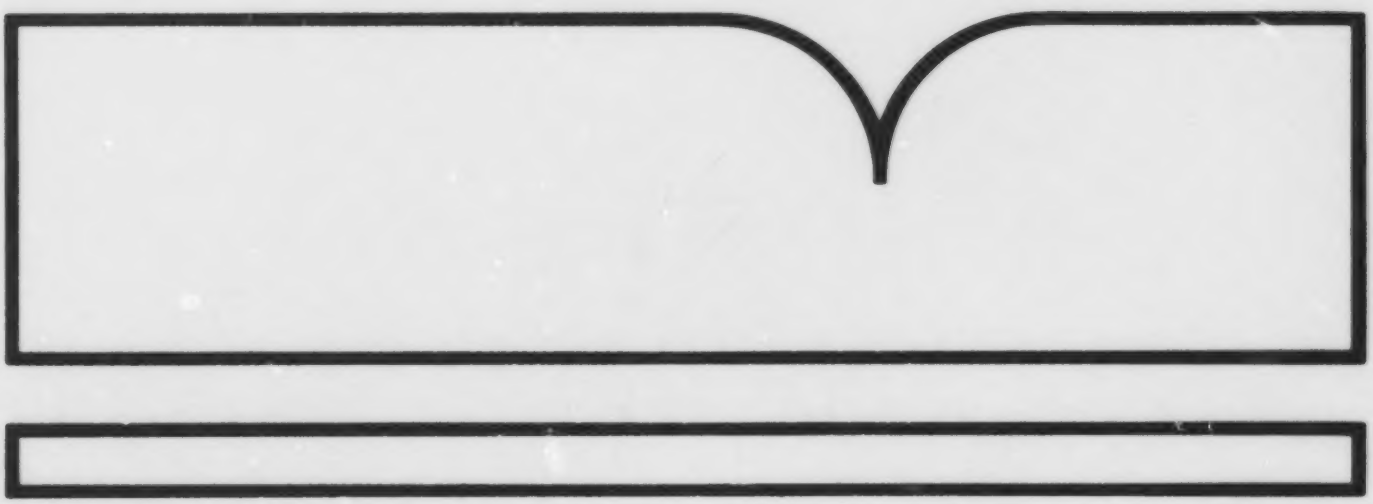

U.S. Department of Commerce
National Technical Information Service
NTIS.

PB86-169414

GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

TRIMETHACARB
(102401)

CASE NUMBER 112

CAS 2686-99-9

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazards that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers

of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, <u>will</u> be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY ASSESSMENT

A. INTRODUCTION

This chapter contains the Agency's regulatory position and rationale on products containing the pesticide trimethacarb as a sole active ingredient. The Agency bases its position and rationale on a consideration of all uses of trimethacarb appearing on pesticide products registered under Sections 3 and 24(c) of FIFRA as well as on products authorized for distribution in intrastate commerce under 40 CFR §162.17. The Agency has reviewed the known chemical, environmental, and toxicological characteristics of this pesticide and its established tolerances for residues in or on corn. Based on this information, the Agency has established data and labeling requirements that must be met by registrants and applicants for registration of trimethacarb manufacturing-use products (MPs) in order for their products to be registered or reregistered under this Standard. Unique labeling requirements and certain data needs for end-use products (EPs) containing trimethacarb are also established by this Standard.

Only those data and labeling requirements for current MPs and EPs and substantially similar ones registered in the future are addressed here. Applications to register products that differ appreciably from those described in this Standard may be subject to additional data and/or labeling requirements.

B. DESCRIPTION OF CHEMICAL AND USE PROFILE

Trimethacarb is the American National Standard Institute's (ANSI) approved name for an insecticide composed of two isomers that is produced by Union Carbide Agricultural Products Company.

The chemical name for trimethacarb is 3,4,5-trimethylphenyl methylcarbamate and 2,3,5-trimethylphenyl methylcarbamate. Other names include the names Broot®, Landrin® and code names UC 27867 and OMS 597.

Other identifying characteristics and codes are:

Empirical Formula:	$C_{11}H_{15}NO_2$
Molecular Weight:	193.24
CAS Registry Numbers:	2686-99-9 (3,4,5-isomer)
	3971-89-9 (2,3,5-isomer)
Shaughnessy Numbers:	102401 (3,4,5-isomer)
	102402 (2,3,5-isomer)

Technical trimethacarb is a buff to brown crystalline powder with a mild ester odor. The melting point is 105-114 °C. Trimethacarb is soluble in water to 58 ppm at 23 °C and hydrolyzes to trimethylphenols, CO_2, and methylamine at pH values greater than pH 8.

Union Carbide Agricultural Products Company is the sole producer of trimethacarb and markets two EPs under the trade name Broot®. These are a 15% granular formulation and a 50% wettable powder formulation. There are no intrastate products. There are no federally registered MPs containing trimethacarb.

Trimethacarb is registered to control corn rootworm on field corn and popcorn. Application is made once per season at planting. Tolerances for food/feed items are currently expressed as the sum of the residues of both isomeric components of trimethacarb [the sum of 3,4,5 and 2,3,5-trimethacarb] (40 CFR 180.305).

C. REGULATORY POSITION AND RATIONALE

Based on a review and evaluation of all available data and other relevant information on trimethacarb, the Agency has made the following determinations:

1. All products containing trimethacarb as a sole active ingredient may continue to be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Guidance Document. Registrants must provide or agree to develop additional data, as specified in Tables A, B and C in order to maintain existing registrations or to permit new registrations.

   Rationale: Under FIFRA, the Agency normally does not cancel or withhold registration simply because data are missing or are inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registrations of trimethacarb.

The existing data base, although minimal, and use history do not suggest that there are any hazards to mixers, loaders, or applicators who follow label use directions and precautions. According to the Pesticide Incident Monitoring System (PIMS), there have been no reports of human or domestic animal incidents.

2. The Agency will not allow any significant new uses* to be granted for trimethacarb until the toxicological and residue chemistry data deficiencies identified in Table A have been satisfied.

   Rationale: The Agency is unable to complete a tolerance reassessment of trimethacarb because of residue chemistry and toxicology data gaps. The data requested in Table A are needed for EPA to determine an acceptable daily intake (ADI) level of trimethacarb and its metabolites and to reassess the present tolerances. (Refer to Section G for a discussion of the tolerance reassessment).

* The terminology "significant new use" is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will generally consider a new use to be significant if it would result in an increase in the Theoretical Maximal Residue Concentration (TMRC) of greater than 1%.

The Agency will not allow any significant new uses until the toxicological and residue data have been received, evaluated, and the Agency concludes that new uses are supportable.

3. The Agency is requiring environmental fate data to fully assess trimethacarb's behavior in the environment. Pending the submission of crop rotation data, EPA is requiring a crop rotation restriction for EP labels which only permits planting of crops registered for trimethacarb use in trimethacarb treated soils.

   Rationale: At present, there are no acceptable studies available to assess the environmental fate of trimethacarb. The existing data are insufficient to characterize trimethacarb's degradation, metabolism, dissipation and mobility, including its potential to leach in soils or contaminate groundwater. Trimethacarb is not on the Groundwater Data Call-In List. Also, there are a lack of adequate accumulation data on trimethacarb residues in rotational crops and fish. Because of insufficient crop rotation data, the Agency is imposing the crop rotation label restriction.

4. The required residue chemistry plant metabolism data must demonstrate whether residues of certain manufacturing impurities may occur in the raw agricultural commodity as a result of application of trimethacarb at the registered maximum application rate. The specific chemical names are not included here because they are considered Confidential Business Information.

Rationale: The Agency is aware that one of the manufacturing impurities present in technical trimethacarb was recently classified as a tumorigen in the Registry of Toxic Effects of Chemical Substances. Additionally, the Agency has recently received a study by the National Toxicology Program which suggests that this same impurity is an oncogen and mutagen. The Agency has not yet formally reviewed this study. If, upon review, the Agency concludes that the chemical is an oncogen, a determination will be made as to its potency and potential human exposure so that a hazard assessment can be conducted and appropriate regulatory action can be taken, if necessary. To insure that data will be present to evaluate any potential risk, the Agency is requiring the registrant to submit data indicating whether the impurity will be present, and if so, at what levels in the raw agricultural commodities.

5. In order to more fully assess the impact of trimethacarb on avian, fish and freshwater invertebrate species, an acute avian oral toxicity study, an acute toxicity study on freshwater invertebrates, and environmental fate studies must be conducted and submitted. Using current estimation techniques, no hazard was predicted from the use of trimethacarb to endangered species. Due to toxicity to cold water fish, labeling cautioning against exposing fish is required. Refer to section F(d)(1)and(2) for the required labeling statements.

Rationale: Based on studies available to assess potential hazards to avian and aquatic organisms, technical trimethacarb is characterized as slightly toxic to birds on a dietary basis and moderately to highly toxic on an acute oral basis. Available data are adequate to demonstrate that technical trimethacarb is highly toxic to cold water fish species. Accordingly, labeling indicating toxicity to fish, required by 40 CFR 162.10 (h)(2)(ii)(B) must be added to the label. There are no available data on trimethacarb's effects on freshwater aquatic invertebrates. Once the Agency has reviewed the required environmental fate data, acute avian oral toxicity data, and the acute toxicity data on freshwater invertebrates, the toxicity of this compound can be reevaluated and an exposure assessment can be made to determine the hazard potential of trimethacarb's use.

6. Studies on trimethacarb's acute, subchronic, and chronic mammalian toxicity must be submitted. Acute oral toxicity data in the rat and dog place the technical trimethacarb in Toxicity Category II. Acute dermal toxicity data in the rabbit place technical trimethacarb in Toxicity Category III.

Rationale: The existing toxicology data base is inadequate to characterize trimethacarb's toxicity, except for acute oral and dermal effects and subchronic dermal effects. A teratology study in rats, which is considered only of supplemental value due to reporting of data deficiencies suggests that trimethacarb is not teratogenic at the doses tested.

When trimethacarb tolerances were originally established, a 90-day dog and rat feeding studies and a 2-year rat feeding study were used to support these tolerances. Upon reevaluation, a no observable effect level (NOEL) could not be determined because these data have been found to be unacceptable due to study design and reporting of data deficiencies. However, they do not suggest any adverse effects. The existing toxicology data base does not include any studies conducted by Industrial Bio-Test Laboratories, Inc. Additional acute, subchronic and chronic toxicology are needed to support the current tolerances and use levels on corn.

7. Registrants of MPs and EPs must submit revised labeling which incorporates the label precautions found in Section F.

Rationale: The Agency believes that label statements prescribed in this Guidance Document should minimize the acute hazards to users of trimethacarb and to terrestrial and aquatic organisms.

Acute toxicity data on freshwater fish indicate that precautionary labeling is required. This requirement is addressed in Section F. The required acute toxicity precautionary statements are specified in 40 CFR 162.10.

D. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To conform to this Guidance Document, products must contain trimethacarb as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern listed in the attached index of the registered uses.

The application for registration or reregistration of manufacturing-use and end-use products subject to this Guidance Document must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, certification of ingredients statement, revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C.

136(c)(1)(D) and 136(c)(2)(D). Registrants of end-use products who qualify for the Formulator's Exemption must submit five (5) copies of draft labeling incorporating the unique labeling statements identified in Section F.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To conform to this Guidance Document, manufacturing-use products and end-use products must contain trimethacarb as the sole active ingredient. Each MP and EP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients which will be present in products.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, manufacturing-use and end-use products containing trimethacarb, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed. The attached index entry lists all registered uses (and intrastate label uses*) as well as approved maximum application rates and frequencies.

* Intrastate uses have not been reviewed for acceptability under sec. 3 of the FIFRA. Therefore, these uses may not be added to any product registered under sec. 3 until the supporting data have been submitted, reviewed, and found to be acceptable.

F. REQUIRED LABELING

All manufacturing-use and end-use trimethacarb products must bear appropriate labeling as specified in 40 CFR 162.10. In addition to the above, the following information must appear on the labeling:

a. Ingredient Statement

The ingredient statement for MPs and EPs must list the active ingredient as:

Trimethacarb (3,4,5-trimethylphenyl methylcarbamate mixture with 2,3,5 trimethylphenyl methylcarbamate approximately 4:1) . . . . . %.

b. Use Pattern Statements

All MP trimethacarb products must state that they are intended for formulation into other manufacturing-use products or end-use products for uses accepted by the U. S. Environmental Protection Agency.

A limiting factor will be data that support the use pattern. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern. The attached "EPA Index to Registered Pesticides" entry summarizes the currently acceptable use for trimethacarb including site of application, target pests, dosage rates, restrictions and limitations, and the method and frequency of application.

c. Acute Toxicity Precautionary Statements

Labels for MPs and EPs must bear statements reflecting the compound's acute human toxicity. The acute oral toxicity data are sufficient to categorize the current EP formulations as Toxicity Category II. The required precautionary statements associated with this category are specified in 40 CFR 162.10.

d. Environmental Hazards Statements

1. The following revised environmental hazard statement must appear on all MP labels:

"ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

2. For end-use products revise the existing environmental hazards statement must read:

"ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands. Drift and runoff from treated areas may be hazardous to fish in neighboring aquatic sites. Do not contaminate water by cleaning of equipment or disposal of waster."

e. Crop Rotation Statement

For EPs, the product label must include the crop rotation statement in the use directions:

"Do not plant crops used for food or feed which are not registered for use with trimethacarb in soils previously treated with this chemical."

G. TOLERANCE REASSESSMENT

U.S. tolerances for neglible residues of trimethacarb in or on raw agricultural commodities are as follows (40 CFR 180.305):

0.1 ppm in or on corn grain (including field corn and popcorn), corn fodder and forage.

There are no international tolerances or Codex Maximum Residue Limits (MRLs) for residues of trimethacarb in or on corn grain or in animal products.

It is concluded that the plant metabolism of trimethacarb is not adequately described because residues in mature corn kernels were not qualitatively and quantitatively characterized. Additional data are necessary to characterize the distribution and metabolism of trimethacarb in the mature corn plant.

Although no tolerances exist for residues of trimethacarb in animal products, the nature of the residue in animals is adequately understood at this time. Trimethacarb or its animal metabolites do not accumulate in edible tissue of cattle. In a cattle feeding study, no ^{14}C residues were detectable in the muscle, fat or kidney of cattle which were fed radiolabeled trimethacarb. However, if the requested plant metabolism data reveal additional metabolites of toxicological concern, the conclusions regarding the nature of residues in animals may change and additional animal metabolism data will be required.

The residue analytical methods for enforcement of tolerances covering the sum of the residues of 3,4,5- and 2,3,5-trimethacarb in or on plant commodities are adequate. However, if the requested plant metabolism data reveal additional metabolites of toxicological concern or if the present residue analytical methods will not adequately determine all conjugated residues of concern then submission of additional validated methods for data collection and tolerance enforcement will be required.

U.S. tolerances for corn grain, fodder and forage are not supported by the available residue chemistry data.

Additional data required are as follows:

1. Data depicting residues in or on mature field corn grain harvested 90 days after application according to label use directions.

2. Residue data are required for corn oil and milled products to determine whether or not residues concentrate. (If residues do concentrate in any of the processed products, the registrant is required to submit a petition for tolerances. However, if food additive tolerances are necessary and if other required residue data demonstrate the presence of any impurities that are shown to be oncogenic (see Section C.4., above), there will be a conflict with the section 409 of the Federal Food, Drug and Cosmetic Act. This section prohibits the establishment of food additive tolerances for additives found to be carcinogenic).

3. Additional data are required that depict residues in or on corn forage, fodder and silage harvested after a single at-planting application. A pregrazing interval must be established and a tolerance for residues in or on silage must be established.

The chronic toxicology studies used to support these tolerances (a 90 day dog feeding study, a 2 year rat feeding study and a 90 day rat feeding study) upon

reevaluation have been found to be inadequate.

The adequacy of the established tolerances covering residues of trimethacarb on or on corn grain, forage, and fodder cannot be determined at the present time due to significant gaps in residue chemistry and toxicology. At present, no acceptable toxicology study exists for calculation of the acceptable daily intake (ADI) or provisional acceptable daily intake (PADI). Until acceptable data are submitted no ADI can be calculated. Data gaps are discussed in Table A.

A permanent tolerance of 0.1 ppm was granted for corn grain which results in a theoretical maximum residue contribution (TMRC) of 0.0016 mg/day for a 1.5 kg diet.

U.S. Tolerances

Crop	Maximum Residue Limit (PPM)
field corn (grain)	0.1
popcorn (grain)	0.1
corn forage	0.1
corn fodder	0.1

No Codex, Mexican, or Canadian tolerances exist for trimethacarb in or on corn.

TRIMETHACARB*

TYPE PESTICIDE: Insecticide

FORMULATION:
G (15%)
WP (50%)

GENERAL WARNINGS AND LIMITATIONS: Trimethacarb is toxic to fish. Do not apply directly to water or wetlands. Drift and runoff from treated areas may be hazardous to fish in neighboring areas.

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Do not plant any food or feed crop other than those with registered trimethacarb treated soils.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Corn (field corn and popcorn)		0.1 ppm corn grain (including field corn and popcorn) and corn fodder and forage (such tolerances to cover the sum of the residues of both components) 90-day preharvest interval through 1.2 ounces per 1,000 feet of row or 1.35 pounds per acre at 30-inch row spacing, for soil application at planting (band).

*Broot
3,4,5-trimethylphenyl methylcarbamate and 2,3,5-trimethylphenyl methylcarbamate

TRIMETHACARB

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Corn rootworms (continued)	1.2 oz/1,000 ft of row or 1-1.31 lb/A [30-40 inch row spacing] (15% G) or 0.9-1.2 oz/1,000 ft of row (50% WP) or 0.75-1.35 lb/A [30-40 inch row spacing] (50% WP)	Soil application at planting (band). Apply a 6 to 8 inch band over the row. Incorporate by applying behind the covering disc and ahead of the press wheel. Apply wettable powder in a minimum of 6 to 8 gallons of water per 13,068 linear feet (equivalent to 1 acre with 40-inch row spacing). Amount applied per acre depends on row spacing.

EPA Index to Pesticide Chemicals

TRIMETHACARB

Listing of Registered Pesticide Products by Formulation

15% granular
trimethacarb (102401 and 102402)
000264-00381

50% wettable powder
trimethacarb (102401 and 102402)
000264-00382

EPA Index to Pesticide Chemicals

TRIMETHACARB

Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number

Corn
Corn rootworms
(15% G)
000264-00381

(50% WP)
000264-00382

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: TRIMETHACARB

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	[X]	[ ]	2	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	[ ]	[X]		
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	[X]	[ ]	3	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R	[X]	[ ]	4	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	[ ]	[x]		
63-3 - Physical State	TGAI	R	[ ]	[x]		
63-4 - Odor	TGAI	R	[ ]	[x]		
63-5 - Melting Point	TGAI	R	[ ]	[x]		

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: TRIMETHACARB

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[X]	[ ]	5	6 Months
63-8 - Solubility	TGAI or PAI	R	[X]	[ ]	6	6 Months
63-9 - Vapor Pressure	PAI	R	[x]	[ ]		6 Months
63-10 - Dissociation constant	PAI	R	[X]	[ ]		6 Months
63-11 - Octanol/water partition coefficient	PAI	R	[x]	[ ]	5	6 Months
63-12 - pH	TGAI	R	[x]	[ ]	5	6 Months
63-13 - Stability	TGAI	R	[x]	[ ]	7	6 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	CR	[ ]	[x]		

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

§158.120 Product Chemistry

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated time frames, which begin on the date of the Guidance Document. (See front cover for the date).

2/ Details of the manufacturing process including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, the purification procedures and quality control measures for the unregistered technical must be submitted.

3/ Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present for which a certified limit is required. Data regarding the accuracy of the methods used to determine the active ingredient and impurities in the samples of the technical product must be submitted.

4/ Qualitative methods to determine trimethacarb and all impurities in the technical product are needed. Each method must be accompanied by validation studies of the accuracy of the method.

5/ The temperature at which the assay was run is needed.

6/ The solubility of the technical in polar and non-polar solvents at 20°C or 25°C must be reported in g/100ml or mg/kg.

7/ Information must be submitted as to the sensitivity of the technical product to metal ions and metal.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL : TRIMETHACARB

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission 2/
§158.125 Residue Chemistry				
171-2 - Chemical Identity	TGAI	Yes	00130616	No
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	00070071 00095891 00095892 00095893 00095928	Yes 3/ 24 Months
- Livestock	PAIRA and Plant Metabolites	Yes	00070071 00095928	Reserved 4/
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	Yes	00070664 00070967 00095900 00095904 00095906 00095907 00095908 00095909 GS0112001	Reserved 5/

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL : TRIMETHACARB

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
- Cereal Grains Group 6/				
o Crop - Corn				
-- Crop field trials	TEP	Partially	00070967	Yes 7/ 42 Months
-- Processed Food/Feed	EP	No	-	Yes 8/ 42 Months
-- Meat/Milk/Poultry/Eggs	TGAI or Plant	Yes	00070662 00070072	No 9/
- Forage, Fodder, and Straw of Cereal Grains Group 10/				
o Corn, forage fodder silage				
-- Crop Field Trials	TEP	Partially	00070967 00095900	Yes 11/ 42 Months
-- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Yes	00070662 00070072	No 9/

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

§158.125 Residue Chemistry - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted within the indicated time frames, which begin on the date of the Guidance Document. (See front cover for the date).
3/ Additional metabolism data are required to reflect the distribution and metabolism of ring-labeled [^{14}C]3,4,5- and 2,3,5-trimethacarb in mature corn (foliage and grain) following at-planting application. There is a concern about the presence of certain manufacturing impurities in technical trimethacarb because one of these impurities was recently classified as a tumorigen in the Registry of Toxic Effects of Chemical Substances. The registrant must indicate whether residues of this compound and the other compounds listed may result in the in raw agricultural commodity as a result of the maximum registered use. Refer to CBI attachment for identification of impurities.
4/ If the requested plant metabolism data reveal additional metabolites of toxicological concern, the nature of the residue in animals may change.
5/ If the requested plant metabolism data reveal additional metabolites of toxicological concern or if the methods will not adequately determine all conjugated residues of concern, then additional validated methods for data collection and tolerance enforcement will be required.
6/ A crop group tolerance is not appropriate at the present time because additional residue data would be required for four additional group members (fresh sweet corn, rice, sorghum and wheat).
7/ Additional data depicting residues in or on mature field corn grain harvested 90 days after a single at-planting application with 50% WP and, in separate tests, the 15% G formulation at 1.35 lb a.i./A must be submitted. Tests must be conducted in Indiana, Illinois, and Minnesota or Nebraska.
8/ Residue data are required for corn oil (crude and refined) and milled products (starch, grits, meal, and flour). These byproducts must be prepared from field corn grain bearing detectable weathered residues. If residues concentrate in any of these processed products, appropriate food additive tolerances must be proposed that may be impacted by the Delaney clause. Refer to footnote #3.
9/ No tolerances are established for residues of trimethacarb in animal products. The nature of the residues in animals has been adequately delineated at the present time. (If the required plant metabolism data indicate the presence of real residues in feed commodities or if tolerances reflecting real residues are requested for any additional feed items, additional animal metabolism data and possibly additional ruminant and poultry feeding studies will be required.)
10/ A crop group tolerance is not appropriate at the present time because residue data would be required for additional group members (wheat and one other cereal grain crop).
11/ Additional data depicting residues in or on corn forage, fodder and silage harvested after a single at-planting application with the 50% WP and, in separate tests, the 15% G formulation at 1.35lb a.i./A must be submitted. Samples of fodder and silage must be collected 90 days after treatment. Samples of forage must be collected at intervals following treatment and a pregrazing internval must be proposed. Tests must be conducted in Indiana, Illinois, and Minnesota or Nebraska. A tolerance for residues in or on silage must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A	No	-	Yes	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A	No	-	Yes	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	No	-	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A	No	-	Yes	27 Months
164-5 - Soil, Long-term	TEP	A	No	-	Reserved 4/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes /5	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved /6	
165-4 - In Fish	TGAI or PAIRA	A	No	-	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

§158.130 Environmental Fate - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frames, which begin on the date of the Guidance Document. (See front cover for this date).
4/ Data will be required if soil residues do not reach 50 percent dissipation prior to recommended subsequent application to the same site as indicated by results of 162-1 or 164-1.
5/ For crops rotated on treated areas, any one of the following will apply to preclude a crop rotation restriction:
(a). A tolerance must be obtained for the rotated crop.
(b). Data must be provided to determime time intervals at which rotated crops planted on treated areas will be free of trimethacarb residues.
6/ Requirement reserved pending results of confined rotational crop studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A	Yes	00128130	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	Yes	00128130	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	No	-	Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A	Partial	00051311 00051312 00070659	Yes 4/	12 Months
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding : - Rodent, and	TGAI	A	No	-	No 5/	
- Non-rodent (Dog)		A	No	-	No 5/	
82-2 - 21-Day Dermal - Rabbit	TGAI	A	Yes	00070656	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:	TGAI					
- Rodent, and		A	No	-	Yes	50 Months
- Non-rodent (Dog)		A	No	-	Yes	50 Months
83-2 - Oncogenicity - 2 species:	TGAI					
- Rat (preferred), and		A	No	-	Yes	18 Months
- Mouse (preferred)		A	No	-	Yes	18 Months
83-3 - Teratogenicity - 2 species:	TGAI					
- Rat		A	Partial	GS0112020	Yes 6/	6 Months
- Rabbit		A	Partial	GS0112021	Yes 7/	6 Months
83-4 - Reproduction - Rat 2-generation	TGAI	A	No	-	Yes	39 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A	No	-	Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A	No	-	Yes	12 Months
84-4 - Other Genotoxic Effects	TGAI	A	No	-	Yes	12 Months
SPECIAL TESTING:						
85-1- General Metabolism	PAI or PAIRA	A	No	-	Yes	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

§158.135 Toxicology - Continued

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frames, which begin on the date of the Guidance Document. (See front cover for this date).
4/ Although delayed neurotoxicity studies are not usually required for a carbamate, the unusual observations noted in the studies conducted (positive for delayed neurotoxicity) require an adequate explanation or additional studies to be submitted.
5/ This data is not required at this time because Union Carbide is in the process of conducting chronic feeding studies. These studies will be required if the chronic studies are not submitted.
6/ The following data needs to be submitted: individual maternal weight data at the intervals measured and historical control data relative to cesarean section observations and fetal malformation and variation observations. The historical data should be presented by individual study and dated and should cover a period of 2 years prior to initiation of this study and any studies conducted after study termination using the Fischer 344 strain from the same vendor.
7/ This study is deficient in that not all fetuses were subjected to skeletal examination after visceral examination as recommeded by the Guidelines. The registrant is, therefore, required to examine those fetuses (which are preserved) for skeletal anomalies and submit the data to the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A	No	-	No 4/
132-1 - Soil Dissipation	TEP	A	No	-	No 4/
133-3 - Dermal Exposure	TEP	A	No	-	No 4/
133-4 - Inhalation Exposure	TEP	A	No	-	No 4/
§158.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	A	No	-	No 4/
201-1 - Drift Field Evaluation	TEP	A	No	-	No 4/

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
4/ No data are required because trimethacarb does not meet the criteria described in 40 CFR 158.140 for reentry data requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A	No	-	Yes	9 Months
71-2 - Avian Subacute Dietary Toxicity	TGAI					
- Upland Game Bird, and		A	Yes	00034769	No	
- Waterfowl		A	Yes	00034769	No	
71-5 - Simulated Field Testing	TEP					
- Mammals, and		A	No		Reserved/4	
- Birds		A	No		Reserved/4	
- Actual Field Testing	TEP					
- Mammals, and		A	No		Reserved/4	
- Birds		A	No		Reserved/4	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity	TGAI					
- Coldwater Fish Species, and		A	Yes	GS0144-012	No	
- Warmwater Fish Species		A	Yes	GS0144-012	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A	No	-	Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frames, which begin on the date of the Guidance Document. (See front cover for this date).
4/ Requirement reserved pending avian single-dose oral LD_{50} data and environmental fate data.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		N/A		No 3/
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		N/A		No 3/
122-1 - Vegetative Vigor	TGAI		N/A		No 3/
122-2 - Aquatic Plant Growth	TGAI		N/A		No 3/
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		N/A		No 3/
123-1 - Vegetative Vigor	TGAI		N/A		No 3/
123-2 - Aquatic Plant Growth	TGAI		N/A		No 3/
TIER III					
124-1 - Terrestrial Field	TEP		N/A		No 3/
124-2 - Aquatic Field	TEP		N/A		No 3/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ These data are not required in accordance with 158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI	A	Yes	00078515	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No	-	No/4
141-4 - Honey bee subacute feeding study					Reserved 5/
141-5 - Field testing for pollinators	TEP	A	No	-	No/4

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.155 Nontarget Insect - Continued					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)/6				
142-1 - Aquatic insect life-cycle study	(Reserved)/6				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)/6				
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3	(Reserved)/6				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frames, which begin upon receipt of the Guidance Document.
4/ Since Trimethacarb is currently registered only at planting and soil incorporation, there is no potential for bee exposure. Thus, testing beyond the first tier is not required.
5/ Reserved pending development of test methodology.
6/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: TRIMETHACARB

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	Yes			2/
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	Yes			2/
61-3 - Discussion of Formation of Impurities	MP	R	Yes			2/
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	Yes			2/
62-2 - Certification of Limits	MP	R	Yes			2/
62-3 - Analytical Methods to Verify Certified Limit	MP	R	Yes			2/
Physical and Chemical Characteristics						
63-2 - Color	MP	R	Yes			2/
63-3 - Physical State	MP	R	Yes			2/
63-4 - Odor	MP	R	Yes			2/

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: TRIMETHACARB

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	Yes			2/
63-12 - pH	MP	CR	Yes			2/
63-14 - Oxidizing or Reducing Action	MP	CR	Yes			2/
63-15 - Flammability	MP	CR	Yes			2/
63-16 - Explodability	MP	R	Yes			2/
63-17 - Storage Stability	MP	R	Yes			2/
63-18 - Viscosity	MP	CR	Yes			2/
63-19 - Miscibility	MP	CR	Yes			2/
63-20 - Corrosion Characteristics	MP	R	Yes			2/

MP = Manufacturing-use Product; R = Required; CR = Conditionally Required
1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
2/ There are no federally registered manufacturing use products containing trimethacarb. Data will be required for registration of manufacturing use products.

TABLE C

PRODUCT SPECIFIC REQUIREMENTS FOR END USE PRODUCTS CONTAINING CHEMICAL: TRIMETHACARB

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-2 - Description of Beginning Materials and Manufacturing Process	EP	R	[X]	[ ]	_____	6 Months
61-3 - Discussion of Formation of Impurities	EP	R	[X]	[ ]	_____	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	EP	CR	[X]	[ ]	_____	12 Months
62-2 - Certification of Limits	EP	R	[X]	[ ]	_____	12 Months
62-3 - Analytical Methods to Verify Certified Limits	EP	R	[X]	[ ]	_____	12 Months
Physical and Chemical Characteristics						
63-2 - Color	EP	R	[X]	[ ]	_____	6 Months
63-3 - Physical State	EP	R	[X]	[ ]	_____	6 Months
63-4 - Odor	EP	R	[X]	[ ]	_____	6 Months
63-5 - Melting Point	TGAI	R	[X]	[ ]	_____	6 Months

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING CHEMICAL: TRIMETHACARB

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	EP	R	[X]		_____	6 Months
63-12 - pH	EP	CR	[X]		_____	6 Months
63-13 - Stability	TGAI	R	[X]		_____	6 Months
63-14 - Oxidizing or Reducing action	EP	CR	[X]		_____	6 Months
63-15 - Flammability	EP	CR	[X]		_____	6 Months
63-16 - Explodability	EP	R	[X]		_____	6 Months
63-17 - Storage Stability	EP	R	[X]		_____	15 Months
63-20 - Corrosion Characteristics	EP	R	[X]		_____	6 Months

EP = End-use Product; TGAI= Technical Grade of the active ingredient; R = Required; CR = Conditionally Required
1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	No		Yes 2/
81-2 - Acute Dermal Toxicity - Rabbit	MP	No		Yes 2/
81-3 - Acute Inhalation Toxicity - Rat	MP	No		Yes 2/
81-4 - Primary Eye Irritation - Rabbit	MP	No		Yes 2/
81-5 - Primary Dermal Irritation - Rabbit	MP	No		Yes 2/
81-6 - Dermal Sensitization - Guinea Pig	MP	No		Yes 2/

: : : :

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING CHEMICAL TRIMETHACARB

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	EP	Yes	000128130	No 3/
81-2 - Acute Dermal Toxicity - Rabbit	EP	No	-	Yes 4/ 9 Months
81-3 - Acute Inhalation Toxicity - Rat	EP	No	-	Yes 4/ 9 Months
81-4 - Primary Eye Irritation - Rabbit	EP	No	-	Yes 4/ 9 Months
81-5 - Primary Dermal Irritation - Rabbit	EP	No	-	Yes 4/ 9 Months
81-6 - Dermal Sensitization - Guinea Pig	EP	No	-	Yes 4/ 9 Months

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REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear th misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing Trimethacarb as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing Trimethacarb in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing Trimethacarb alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing Trimethacarb either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Applications and other required information should be submitted to the following address:

Jay S. Ellenberger Product Manager 12
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-2386

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Appendix II-1

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Trimethacarb Standard

MRID CITATION

00034769 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds. By U.S. Fish and Wildlife Service, Patuxent Wildlife Research Center. Washington, D.C.: U.S. FWS. (Special Scientific Report--Wildlife No. 191; report no. 33423a; also in unpublished submission received Mar 28, 1979 under 3125-236; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:237905-B)

00051311 Newell, G.W. (1968) Letter sent to Rene Blondeau dated Jun 10, 1968 [Demyelination potential of SD 8530]: Project No. BC 868-17. Final rept. (Unpublished study received Jun 10, 1968 under unknown admin. no.; prepared by Stanford Research Institute, submitted by Shell Chemical Co., Washington, D.C.; CDL:107992-A)

00051312 Newell, G.W. (1967) Letter sent to Rene Blondeau dated Oct 3, 1967 [Results of demyelination study in laying hens--Technical SD 8530]: Project No. 868-14. Final rept. (Unpublished study received Oct 3, 1967 under unknown admin. no.; prepared by Stanford Research Institute, submitted by Shell Chemical Co., Washington, D.C.; CDL:107991-A)

00070071 Shell Chemical Company (1968) Metabolism Studies. (Unpublished study received Oct 15, 1969 under 9F0843; CDL:091458-N)

00070072 Shell Chemical Company (1968) Residues in Milk from Cow Feeding Studies with Carbamic Acid, Methyl-, 4-(Hydroxymethyl)-3,5-xylyl Ester. (Unpublished study received Oct 15, 1969 under 9F0843; CDL:091458-O)

00070656 Narcisse, J.K. (1967) Letter sent to Rene Blondeau dated Aug 1, 1967 [Results of a repeated dermal toxicity study (rabbit) and a saturated vapor toxicity study (rat) of SD 8530]: Project No. B 868-1, Report No. 44. (Unpublished study received Oct 15, 1969 under 9F0843; prepared by Stanford Research Institute, submitted by Shell Chemical Co., Washington, D.C.; CDL:091458-F)

00070659 Newell, G.W. (1967) Letter sent to Rene Blondeau dated Oct 3, 1967 [Results of a demyelination study, in laying hens, of Technical SD 8530]: Project No. 868-14. Final rept. (Unpublished study received Oct 15, 1969 under 9F0843; prepared by Stanford Research Institute, Dept. of Agricultural and Environmental Toxicology, submitted by Shell Chemical Co., Washington, D.C.; CDL:091458-J)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Trimethacarb Standard

MRID CITATION

00070662 Shell Chemical Company (19??) Residues in Cow Tissues from Feeding Studies with Carbamic Acid, Methyl-, 4-(Hydroxymethyl)-3,5-xylyl Ester. (Unpublished study received Oct 15, 1969 under 9F0843; CDL:091458-P)

00070664 Shell Development Corporation (1966) Determination of SD 8530 Residues in Agricultural Crops: A Tentative Method Involving Column Cleanup and Enzyme Inhibition-spectrophotometric Measurement. Analytical method MMS-78/66 dated Dec 1966. (Unpublished study received Oct 15, 1969 under 9F0843; CDL:091458-S)

00070967 Shell Chemical Company (1968) Residue Data Developed from the Use of Landrin Insecticide on Corn. (Compilation; unpublished study received Oct 14, 1969 under 9F0843; CDL:091456-B)

00078515 Harris, C.R.; Svec, H.J. (1970) Laboratory Studies on the Contact Toxicity of Some Insecticides to Honeybees: Mobay Report No. 28755. (Canada, Dept. of Agriculture, Research Institute; unpublished study; CDL:120480-AL)

00095891 Shell Development Company (1968) Liquid Scintillation Counting of 14C. Method MMS-110/68 dated Oct 1968. (Unpublished study received Aug 1, 1972 under 9F0843; CDL:093139-G)

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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on) the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27983, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.18, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement.*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC$_{50}$	Up to and including 2 mg/liter	From 2 thru 20 mg/liter	From 20 thru 200 mg/liter	Greater than 200 mg/liter
Dermal LD$_{50}$	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive, corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word.*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment.*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practi

cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	8
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed (inhaled or absorbed through skin). Do not breathe vapor (dust or spray mist). Do not get in eyes, on skin, or on clothing (Front panel statement of practical treatment required.)	Corrosive, causes eye and skin damage (or skin irritation) Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed (Appropriate first aid statement required.)
II	May be fatal if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Appropriate first aid statements required.)	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed (Appropriate first aid statement required.)
III	Harmful if swallowed (inhaled or absorbed through the skin). Avoid breathing vapors (dust or spray mist) Avoid contact with skin (eyes or clothing) (Appropriate first aid statement required.)	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists
IV	(No precautionary statements required.)	(No precautionary statements required.)

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F. if there is a flashback or any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame. All other pressurized containers	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use.*—(1) *General requirements.*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use.*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28288, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5788, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing.*

(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty

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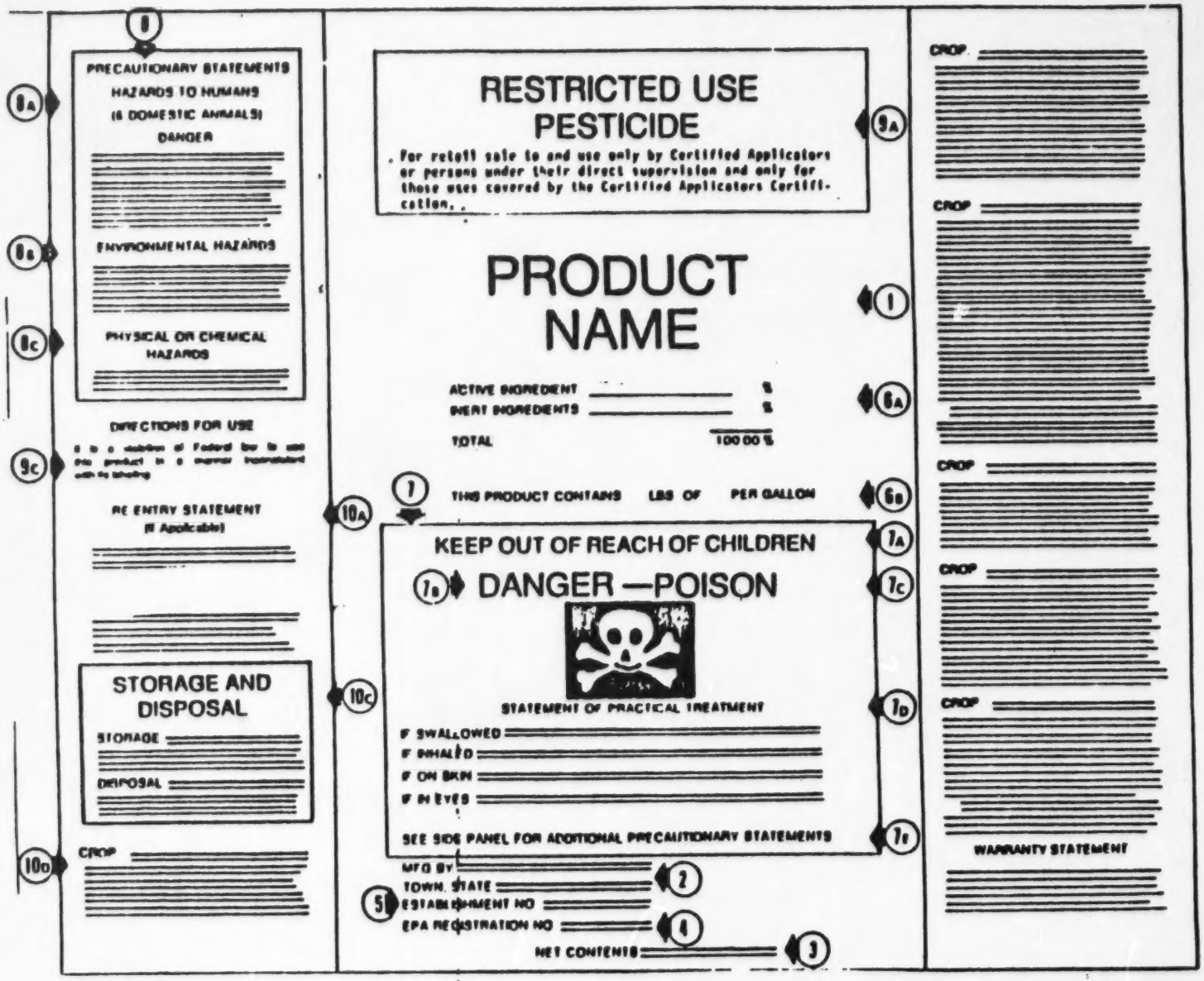
8
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
8A
ENVIRONMENTAL HAZARDS
8B
PHYSICAL OR CHEMICAL
HAZARDS
8C
DIRECTIONS FOR USE
9C
RE ENTRY STATEMENT
(If Applicable)
10A
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10C
CROP
10D
RESTRICTED USE
PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.
9A
PRODUCT
NAME
1
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00 %
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
DANGER —POISON
7B
7C
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
7D
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and now fiber drum may be reused.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, O,O-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene